

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of  
HANUMAN B. JAMPANI ET AL.

Group Art Unit: 1615

U.S. Serial No.: 10/029,506

Confirmation No.: 4582

Filed: December 21, 2001

For: BIO-COMPATIBLE MEANS FOR  
CONTROLLED DRUG DELIVERY  
TO TISSUE AND METHOD OF USE

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Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

In accordance with the provisions of 37 C.F.R. Sections 1.97 and 1.98,  
applicants and their attorney respectfully request that the following patents and  
publications, copies of which are attached hereto, be made of record in the official  
United States Patent and Trademark Office file relating to the above-identified  
application.

U.S. Patents.

5,246,707  
5,618,563  
5,660,854  
5,660,857  
5,700,485  
5,702,716  
5,756,127  
5,766,631  
5,789,465

5,840,338  
5,891,460\*  
5,922,340  
6,015,844  
6,046,187  
6,193,991  
6,214,387  
6,255,502



### Foreign Patent Publications

European Patent Publication No. 0 506 326  
European Patent Publication No. 0 539 751  
European Patent Publication No. 0 562 864\*  
European Patent Publication No. 0 636 377  
European Patent Publication No. 0 636 378\*  
European Patent Publication No. 0 649 662\*  
European Patent Publication No. 0 773 034.  
European Patent Publication No. 1 052 507  
International Patent Publication No. WO 94/05265  
International Patent Publication No. WO 96/16643  
International Patent Publication No. WO 96/34599  
International Patent Publication No. WO 96/40090\*  
International Patent Publication No. WO 97/38737\*  
International Patent Publication No. WO 98/10769  
International Patent Publication No. WO 98/20839  
International Patent Publication No. WO 98/30245  
International Patent Publication No. WO 98/33479  
International Patent Publication No. WO 98/51290  
International Patent Publication No. WO 98/58011  
International Patent Publication No. WO 99/07777  
International Patent Publication No. WO 99/40120  
International Patent Publication No. WO 00/04939\*  
International Patent Publication No. WO 00/05269  
International Patent Publication No. WO 00/33893\*  
International Patent Publication No. WO 00/37138  
International Patent Publication No. WO 01/10468  
International Patent Publication No. WO 01/13901  
International Patent Publication No. WO 01/43749

### Publications

Bogdalkova, D. and Hornova, J., Abstract of "Experimental implantation of traumacel dental pins on the base of carboxycellulose into the corium",  
Scr. Med. Fac. Med. Univ. Brun. Purkynianae, Med. Fac.,  
J.E. Purkyne Univ., Brno, Czech., 1986, pp. 293-297

Curley, J., et al., Abstract of "Prolonged regional nerve blockage: Injectable biodegradable bupivacaine/polyester microspheres", Anesthesiology, Massachusetts Institute of Technology, Children's Hospital, Boston, MA., 1996, pp 1401-1410

Kailasam, S., et al., Abstract of "Maintenance of therapeutically active levels of isoniazid for prolonged periods in rabbits after a single implant of biodegradable polymer", Tubercle and Lung Disease, Dept. of Mycobacteriology Research, Univ. Illinois College of Medicine, Chicago, IL, 1994, pp. 361-365

Leuenberger, K.P., et al., Abstract of "Development of a ceramic device for continuous delivery of acetylsalicylic acid", Proc. South. Biomed. Eng. Conf., 15th Ed., Department of Biology, University of Dayton, Dayton, OH, 1996, pp. 235-238

Ludvik, J., et al., Abstract of "Physicochemical in vitro and in vivo investigation of cinchocaine deposition in atelocollagen felt", Ceska Slov. Farm., Ustav Fyzikalni Chemie J. Heyrovskeho, Prague, Czech Rep., 2000, pp. 185-189

Maniar, M., et al., Abstract of "Controlled release of a local anesthetic from fatty acid dimer based polyanhydride", J. Controlled Release, SCIOS-NOVA Corporation, Baltimore, MD., 1994, pp. 233-239

Menei, P., et al., Abstract of "Drug targeting into the central nervous system by stereotactic implantation of biodegradable microspheres", Neurosurgery, Service de Neurochirurgie, France, 1994, pp. 1,058-1,064

Park E., et al., Abstract of "Biodegradable polyanhydride devices of cefazolin sodium, bupivacaine, and taxol for local drug delivery: preparation, and kinetics and mechanism of in vitro release", Journal of Controlled Release, Dept. of Pharmaceutical Sciences, Medical University of South Carolina, Charleston, SC, 1998, pp 179-189

Rana, J. and Ramzan, I., Abstract of "Neuromuscular blocking drug pharmacodynamics after chronic exposure to H2-antagonists", In Vivo, Department of Pharmacy, University of Sydney, Australia, 1995, pp. 163-165

Applicants' attorney notes that U.S. Patent No. 6,255,502 is discussed and incorporated by reference into the specification of the present application (see page 10 of the specification). In addition, applicants' attorney notes that an English-language translation of International Patent Publication No. WO 98/20839 is presently not available. However, applicants will provide the United States Patent and Trademark Office with appropriate English-language translations upon the Examiner's request for same. In the meantime, applicants' attorney notes that this International Publication contains an English-language abstract.

Of the remaining patents and publications listed above, those which are identified by an asterisk (\*) have been discussed in the specification of the present U.S.

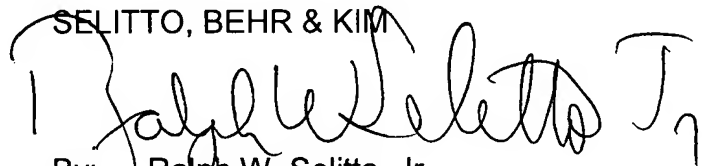
application. The remaining patents and publications are in the English-language and, therefore, additional comments concerning their relevance are considered unnecessary.

In order to facilitate the Examiner's citation of the patents and publications listed above, applicants' attorney has completed United States Patent and Trademark Office Form PTO-1449. The completed Form is attached hereto for the Examiner's convenience.

No fees are believed to be due in connection with the submission of this Information Disclosure Statement. However, if any such fees are due, including extension and petition fees, the Examiner is hereby authorized to charge them to Deposit Account No. 19-1218.


Respectfully Submitted,

SELITTO, BEHR & KIM

A handwritten signature in black ink, appearing to read "Ralph W. Selitto, Jr.", written over the printed name.

By: Ralph W. Selitto, Jr.  
Reg. No. 26,996

203 Main Street  
Metuchen, New Jersey 08840  
(732) 744-1001

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|--|--|---|---------------------------|
| Form PTO 1449  | U.S. Department of Commerce<br>Patent and Trademark Office | Atty. Docket No.<br>ETH-1601 (J&J 3.0-071)                                  | Serial No.<br>10/029, 506 |
|  |  | <b>INFORMATION DISCLOSURE CITATION</b><br>(Use several sheets if necessary) |                           |
|  |  | Applicant<br>HANUMAN B. JAMPANI ET AL.                                      |                           |
|  |  | Filing Date<br>December 21, 2001  | Group Art Unit<br>1615    |

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| *Examiner Initial |    | Document Number |   |   |   |   |   |   | Date     | Name           | Class | Sub-class | Filing Date If Appropriate |
|-------------------|----|-----------------|---|---|---|---|---|---|----------|----------------|-------|-----------|----------------------------|
|                   | AA | 5               | 2 | 4 | 6 | 7 | 0 | 7 | 9/21/93  | Haynes         |       |           |                            |
|                   | AB | 5               | 6 | 1 | 8 | 5 | 6 | 3 | 4/8/97   | Berde et al.   |       |           |                            |
|                   | AC | 5               | 6 | 6 | 0 | 8 | 5 | 4 | 8/26/97  | Haynes et al.  |       |           |                            |
|                   | AD | 5               | 6 | 6 | 0 | 8 | 5 | 7 | 8/26/97  | Haynes et al.  |       |           |                            |
|                   | AE | 5               | 7 | 0 | 0 | 4 | 8 | 5 | 12/23/97 | Berde et al.   |       |           |                            |
|                   | AF | 5               | 7 | 0 | 2 | 7 | 1 | 6 | 12/30/97 | Dunn et al.    |       |           |                            |
|                   | AG | 5               | 7 | 5 | 6 | 1 | 2 | 7 | 5/26/98  | Grisoni et al. |       |           |                            |
|                   | AH | 5               | 7 | 6 | 6 | 6 | 3 | 1 | 6/16/98  | Arnold         |       |           |                            |
|                   | AI | 5               | 7 | 8 | 9 | 4 | 6 | 5 | 8/4/98   | Harvey et al.  |       |           |                            |
|                   | AK | 5               | 8 | 4 | 0 | 3 | 3 | 8 | 11/24/98 | Roos et al.    |       |           |                            |

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|-------------------|----|-----------------|---|---|---|---|---|---|---------|--------|-------|-----------|-------------|----|
|                   |    |                 |   |   |   |   |   |   |         |        |       |           | Yes         | No |
|                   | AL | 0               | 5 | 0 | 6 | 3 | 2 | 6 | 9/30/92 | Europe |       |           |             |    |
|                   | AM | 0               | 5 | 3 | 9 | 7 | 5 | 1 | 5/5/93  | Europe |       |           |             |    |
|                   | AN | 0               | 5 | 6 | 2 | 8 | 6 | 4 | 9/29/93 | Europe |       |           |             |    |
|                   | AO | 0               | 6 | 3 | 6 | 3 | 7 | 7 | 2/1/95  | Europe |       |           |             |    |
|                   | AP | 0               | 6 | 3 | 6 | 3 | 7 | 8 | 2/1/95  | Europe |       |           |             |    |
|                   | AQ | 0               | 6 | 4 | 9 | 6 | 6 | 2 | 4/26/95 | Europe |       |           |             |    |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Page, Etc.)

|    |   |
|----|---|
| AR | Bogdalkova, D. and Hornova, J., Abstract of "Experimental implantation of traumacel dental pins on the base of carboxycellulose into the corium", Scr. Med. Fac. Med. Univ. Brun. Purkynianae, Med. Fac., J.E. Purkyne Univ., Brno, Czech., 1986, pp. 293-297   |
| AS | Curley, J., et al., Abstract of "Prolonged regional nerve blockage: Injectable biodegradable bupivacaine/polyester microspheres", Anesthesiology, Massachusetts Institute of Technology, Children's Hospital, Boston, MA., 1996, pp 1401-1410   |
| AT | Kailasam, S., et al., Abstract of "Maintenance of therapeutically active levels of isoniazid for prolonged periods in rabbits after a single implant of biodegradable polymer", Tubercle and Lung Disease, Dept. of Mycobacteriology Research, Univ. Illinois College of Medicine, Chicago, IL, 1994, pp. 361-365 |

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## INFORMATION DISCLOSURE CITATION

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Applicant  
HANUMAN B. JAMPANI ET AL.Filing Date  
December 21, 2001Group Art Unit  
1615

## U. S. PATENT DOCUMENTS

| *Examiner Initial |    | Document Number |   |   |   |   |   |   | Date    | Name           | Class | Sub-class | Filing Date If Appropriate |
|-------------------|----|-----------------|---|---|---|---|---|---|---------|----------------|-------|-----------|----------------------------|
|                   | AA | 5               | 8 | 9 | 1 | 4 | 6 | 0 | 4/6/99  | Rodgers et al. |       |           |                            |
|                   | AB | 5               | 9 | 2 | 2 | 3 | 4 | 0 | 6/13/99 | Berde et al.   |       |           |                            |
|                   | AC | 6               | 0 | 1 | 5 | 8 | 4 | 4 | 1/18/00 | Harvey et al.  |       |           |                            |
|                   | AD | 6               | 0 | 4 | 6 | 1 | 8 | 7 | 4/4/00  | Berde et al.   |       |           |                            |
|                   | AE | 6               | 1 | 9 | 3 | 9 | 9 | 1 | 2/27/01 | Shukla         |       |           |                            |
|                   | AF | 6               | 2 | 1 | 4 | 3 | 8 | 7 | 4/10/01 | Berde et al.   |       |           |                            |
|                   | AG | 6               | 2 | 5 | 5 | 5 | 0 | 2 | 6/3/01  | Penkler et al. |       |           |                            |
|                   | AH |                 |   |   |   |   |   |   |         |                |       |           |                            |
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|                   | AL | 0               | 7 | 7 | 3 | 0 | 3 | 4 | 5/14/97  | Europe        |       |           |             |    |
|                   | AM | 1               | 0 | 5 | 2 | 5 | 0 | 7 | 11/15/00 | Europe        |       |           |             |    |
|                   | AN | 9               | 4 | 0 | 5 | 2 | 6 | 5 | 3/17/94  | International |       |           |             |    |
|                   | AO | 9               | 6 | 1 | 6 | 6 | 4 | 3 | 6/6/96   | International |       |           |             |    |
|                   | AP | 9               | 6 | 3 | 4 | 5 | 9 | 9 | 11/7/96  | International |       |           |             |    |
|                   | AQ | 9               | 6 | 4 | 0 | 0 | 9 | 0 | 12/19/96 | International |       |           |             |    |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Page, Etc.)


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|  | AR | Leuenberger, K.P., et al., Abstract of "Development of a ceramic device for continuous delivery of acetylsalicylic acid", Proc. South. Biomed. Eng. Conf., 15th Ed., Department of Biology, University of Dayton, Dayton, OH, 1996, pp. 235-238 |  |  |  |  |  |  |  |  |  |  |  |
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|  | AS | Ludvik, J., et al., Abstract of "Physicochemical in vitro and in vivo investigation of cinchocaine deposition in atelocollagen felt", Ceska Slov. Farm., Ustav Fyzikalni Chemie J. Heyrovskeho, Prague, Czech Rep., 2000, pp. 185-189           |  |  |  |  |  |  |  |  |  |  |  |
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|  | AT | Maniar, M., et al., Abstract of "Controlled release of a local anesthetic from fatty acid dimer based poyanhydride", J. Controlled Release, SCIOS-NOVA Corporation, Baltimore, MD., 1994, pp. 233-239   |  |  |  |  |  |  |  |  |  |  |  |
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| Form PTO-1449   | U.S. Department of Commerce<br>Patent and Trademark Office | Atty. Docket No.<br>ETH-1601 (J&J 3.0-071) | Serial No.<br>10/029, 506 |
|  <p><b>INFORMATION DISCLOSURE CITATION</b><br/>         (Use several sheets if necessary)</p> |  | Applicant<br>HANUMAN B. JAMPANI ET AL.     |                           |
|   |  | Filing Date<br>December 21, 2001           | Group Art Unit<br>1615    |

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|                   |    |                 |          |               |       |           | Yes         | No |
|                   | AL | 9 7 3 8 7 3 7   | 10/23/97 | International |       |           |             |    |
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|                   | AN | 9 8 2 0 8 3 9   | 5/22/98  | International |       |           |             |    |
|                   | AO | 9 8 3 0 2 4 5   | 7/16/98  | International |       |           |             |    |
|                   | AP | 9 8 3 3 4 7 9   | 8/6/98   | International |       |           |             |    |
|                   | AQ | 9 8 5 1 2 9 0   | 11/19/98 | International |       |           |             |    |

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|  | AR | Menei., P., et al., Abstract of "Drug targeting into the central nervous system by stereotactic implantation of biodegradable microspheres", Neurosurgery, Service de Neurochirurgie, France, 1994, pp. 1,058-1,064  |
|  | AS | Park E., et al., Abstract of "Biodegradable polyanhydride devices of cefazolin sodium, bupivacaine, and taxol for local drug delivery: preparation, and kinetics and mechanism of in vitro release", Journal of Controlled Release, Dept. of Pharmaceutical Sciences, Medical University of South Carolina, Charleston, SC, 1998, pp 179-189 |
|  | AT | Rana, J. and Ramzan, I., Abstract of "Neuromuscular blocking drug pharmacodynamics after chronic exposure to H2-antagonists", In Vivo, Department of Pharmacy, University of Sydney, Australia, 1995, pp. 163-165  |

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| Form PTO-1449<br><div style="border: 1px solid black; border-radius: 50%; width: 100px; height: 100px; display: flex; align-items: center; justify-content: center; margin: 10px auto;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg); font-weight: bold;">             O I P E<br/>             AUG 26 2002<br/>             PATENT &amp; TRADEMARK OFFICE           </div> </div> | U.S. Department of Commerce<br>Patent and Trademark Office | Atty. Docket No.<br>ETH-1601 (J&J 3.0-071) | Serial No.<br>10/029, 508 |
| INFORMATION DISCLOSURE CITATION<br>(Use several sheets if necessary)  |  | Applicant<br>HANUMAN B. JAMPANI ET AL.     |                           |
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**FOREIGN PATENT DOCUMENTS**

| *Examiner Initial |    | Document Number | Date     | Name          | Class | Sub-class | Translation |    |
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|                   | AL | 9 8 5 8 0 1 1   | 12/23/98 | International |       |           |             |    |
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|                   | AN | 9 9 4 0 1 2 0   | 8/12/99  | International |       |           |             |    |
|                   | AO | 0 0 0 4 9 3 9   | 2/3/00   | International |       |           |             |    |
|                   | AP | 0 0 0 5 2 6 9   | 2/3/00   | International |       |           |             |    |
|                   | AQ | 0 0 3 3 8 9 3   | 6/15/00  | International |       |           |             |    |


**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Page, Etc.)**

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|---|--|--|---------------------------|
| Form PTO-1449<br> | U.S. Department of Commerce<br>Patent and Trademark Office | Atty. Docket No.<br>ETH-1601 (J&J 3.0-071) | Serial No.<br>10/029, 506 |
| INFORMATION DISCLOSURE CITATION<br>(Use several sheets if necessary)                              |  | Applicant<br>HANUMAN B. JAMPANI ET AL.     |                           |
|   |  | Filing Date<br>December 21, 2001           | Group Art Unit<br>1615    |

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 Sheet 5 of 6

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|                   | AL | 0 0 3 7 1 3 8   | 6/29/00 | International |       |           |             |    |
|                   | AM | 0 1 1 0 4 6 8   | 2/15/01 | International |       |           |             |    |
|                   | AN | 0 1 1 3 9 0 1   | 3/1/01  | International |       |           |             |    |
|                   | AO | 0 1 4 3 7 4 9   | 6/21/01 | International |       |           |             |    |
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